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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,253	01/14/2002	Gregory Cope	CIT1510-4	6270
28213	7590	01/12/2005	EXAMINER	
DLA PIPER RUDNICK GRAY CARY US, LLP			PAK, YONG D	
4365 EXECUTIVE DRIVE			ART UNIT	
SUITE 1100			PAPER NUMBER	
SAN DIEGO, CA 92121-2133			1652	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .	Applicant(s)	
	10/047,253	COPE ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- Th MAILING DATE f this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-37,39,41-57,72 and 73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-37,39,41-57,72 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on October 7, 2004, amending claim 32 and canceling claims 38, 40 and 76, has been entered.

Claims 32-37, 39, 41-57 and 72-73 are pending. Claims 32-37, 39, 41-57 and 72-73 are under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on October 20, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

Terminal Disclaimer

The terminal disclaimer filed on October 7, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 10/340,578 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicant's amendment and arguments filed on October 7, 2004, have been fully considered and are deemed to be persuasive to overcome the rejections previously

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applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-37, 39, 41-57 and 72-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of using a polypeptide having isopeptidase activity comprising the JAMM domain of SEQ ID NOs: 1 and 2. Therefore, these claims are drawn to a method of using a genus of polypeptides having any structure. The specification only teaches a few representative species, culling proteins and COP9 signalosomes. These three species are not enough to describe the whole genus of isopeptidases. Even though the claims do limit the structure of the polypeptide to a polypeptide comprising the JAMM domains, the domain is insufficient in describing the structure of such a wide genus of isopeptidase. Art teaches that the JAMM domain, H-X-H-X₁₀-D (SEQ ID NO:1) is only found in prokaryotes and not in all eukaryotes (Cope et al. – form PTO-1449). A polypeptide comprising only the JAMM domain of SEQ ID

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NOs: 1 or 2, of which only three residues are identified, may or may not have full isopeptidase activity. The specification does not describe which residues of a isopeptidase are needed to impart a polypeptide with isopeptidase activity. Even though the specification describes several isopeptidase comprising a JAMM domain, the genus is drawn to any isopeptidase. Proteins belonging to the family of isopeptidase is large and diverse. Therefore, these claims are drawn to a method of using a genus of polypeptides having any structure.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 32-37, 39, 41-57 and 72-73.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov <<http://www.uspto.gov>>.

Claims 37-46 and 48-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using COP9 Signalosome described in Example 1 in the specification, does not reasonably provide enablement for a method of using polypeptides having isopeptidase activity and having any structure. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a method of using any polypeptide having isopeptidase activity comprising the JAMM domain of SEQ ID NOs: 1 and 2. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Even though the claims do limit the structure of the polypeptide to a polypeptide comprising the JAMM domains, the domain is insufficient in teaching the structure of such a wide genus of isopeptidase. Art teaches that the JAMM domain , H-X-H_{X10}-D (SEQ ID NO:1) is only found in prokaryotes and not in all eukaryotes (Cope et al. – form PTO-1449). A polypeptide comprising only the JAMM domain of SEQ ID NOs: 1 or 2, of which only three residues are identified, may or may not have full isopeptidase activity. The specification does not teach which residues of an isopeptidase are needed to impart a polypeptide with isopeptidase activity. The quantity of experimentation in this area is extremely large and it would require significant study to identify any isopeptidase having the JAMM domains and would be an inventive, unpredictable and difficult

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undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective

Even though the specification describes several isopeptidase comprising a JAMM domain, the claims are drawn to any isopeptidase. Proteins belonging to the family of isopeptidase is large and diverse. The predictability as to the level of conservation between COP9 signalosome and cullin proteins and those of other isopeptidase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of all isopeptidase and their modifier and target proteins. It would require significant study to identify any isopeptidase having the JAMM domains and would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method of using any isopeptidase comprising a JAMM domain with an enormous number of amino acid modifications of the isopeptidase. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient

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guidance, determination of the isopeptidase having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).


None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652



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